

Double-sided back muscle numbing for pain relief pain after having the gallbladder removed using keyhole surgery

Submission date 16/09/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/09/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/09/2023	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Laparoscopic cholecystectomy is a specific type of surgery where the gallbladder is removed using small incisions and a camera. An erector spinae block is a medical procedure in which a local anesthetic (a medication that numbs sensation) is injected near the erector spinae muscles along the spine. This is done to block or numb the nerves that transmit pain signals from the surgical area to the brain. The purpose of using this block is to provide effective pain relief during and after the surgery. By numbing the nerves in the area, it helps reduce the amount of pain the patient feels, making the surgical procedure more comfortable and improving the postoperative recovery experience. It's a part of the overall pain management strategy for the surgery, potentially leading to better pain control and a smoother recovery process for the patient.

Who can participate?

Patients getting laparoscopic cholecystectomy

What does the study involve?

Patients were split into two groups: one receiving general anesthesia plus regular pain control, and the other receiving both of those plus an erector spinae block.

What are the possible benefits and risks of participating?

The potential advantages include better pain relief, while the risks involve the use of ultrasound to guide the block.

Where is the study run from?

Universidad del Sinu (Colombia)

When is the study starting and how long is it expected to run for?

May 2021 to February 2023

Who is funding the study?
Universidad del Sinu (Colombia)

Who is the main contact?
Mauro Causil, jjmoralesb@unal.edu.co

Contact information

Type(s)

Principal investigator

Contact name

Mr Mauro Causil

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

08012021

Study information

Scientific Title

Bilateral erector spinae block for postoperative analgesia in laparoscopic cholecystectomy: A randomized clinical trial

Study objectives

ESPB improves postoperative analgesia and reduces opioid consumption

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 08/01/2021, Clinica La Concepcion Ethics Committee (CALLE 38 52 249 LOS ALPES, Sincelejo, 700001, Colombia; (+57) 5 2749180; info@laconcepcion.org), ref: 08012021

Study design

Prospective interventional randomized clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Improvement of analgesia in patients undergoing laparoscopic cholecystectomy

Interventions

There were 2 study arms: one was general anaesthesia + standard analgesia and the other arm was general anaesthesia + standard analgesia + bilateral US-guided erector spinae block. Follow up was 48 hrs after surgery to record pain scores. The randomization process was done using Epi Dat 4.2.

Intervention Type

Other

Primary outcome(s)

Pain measured using a 0 (least)-10 (worst) pain score 1, 6, 12, 24 and 48 hr after surgery

Key secondary outcome(s)

Requirement of opioid (Yes or No) 1 hour after surgery

Completion date

28/02/2023

Eligibility**Key inclusion criteria**

1. More than 18 years old
2. ASA I,II
3. Undergoing laparoscopic cholecystectomy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Total final enrolment

68

Key exclusion criteria

1. IMC >30
2. Open cholecystectomy
3. Allergy to local anesthetics
4. Recent opioid use

Date of first enrolment

01/08/2021

Date of final enrolment

28/02/2023

Locations

Countries of recruitment

Colombia

Study participating centre

Clinica La Concepcion

CALLE 38 52 249 LOS ALPES

Sincelejo

Colombia

700001

Sponsor information

Organisation

Universidad del Sinú

ROR

<https://ror.org/013ys5k90>

Funder(s)

Funder type

University/education

Funder Name

Universidad del Sinú

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and or analyses during the current study will be available upon request from jjmoralesb@unal.edu.co

IPD sharing plan summary

Available on request